Remarks

Claims 9 and 10 have been rejected under 35 USC 112 as indefinite. Applicants have amended claims 9 and 10 to address this rejection. Applicants respectfully submit this rejection is moot in view of the foregoing amendments.

Claims 1—5, 9 and 10 have been rejected as anticipated by Freed. Freed, however, fails to teach or describe every limitation of claim 1. Specifically, Freed does not teach, describe or suggest

> a second gas-line part part-implantable in the patient and part-external to the patient and having a first end external to the patient for sealing connection to an external driver and a second end implanted in the patient for removable sealing connection with the connection fitting on the second end of the first gas-line part, wherein the connection between the first gas-line part and the second gas-line part is positionable fully within the body of the patient in spaced relation with an exit site in the body of the patient through which the second gas-line part passes, and
>
> a subcutaneous anchoring collar positioned about the second gas-line part positionable fully with the body of the patient in spaced relationship with the exit site in the body and in spaced relationship with the connection between the first gas-line part and the second gas-line part.

as claimed in claim 1. Freed simply does not describe a gas-line with a subcutaneous connection in spaced relation with an exit site in the patient's body and a subcutaneous anchoring collar in spaced relation with an exit site in the patient's body and the subcutaneous connection in the gas line. Freed describes his device and its installation as follows:

About one week before the implantation of the blood pump, the PAD will be implanted. In this surgical procedure, a transverse skin incision is made at the level of L_{1-2} of the left hypogastric region. From this incision a subcutaneous pocket 10 cm in diameter is created, and a circular incision is made in the skin covering the pocket. **The PAD is inserted through the transverse incision into the subcutaneous pocket and exposed through the circular incision.** Care is taken to avoid contact with the PAD fibroblast coating. The pocket is closed using Prolene sutures. (Col. 3, lines 29—38).

The PAD [12] has two main parts as illustrated in FIG. 3: (1) an implanted, 0.75" diameter cylindrical neck with a flexible, cloth-covered flange at a base 16, precoated with fibroblasts and implanted about a week before blood pump insertion, and positioned near the patient's navel, with the flange under the skin, and inside the neck is a replaceable turret; and (2) an **external, detachable part 18 which connects the PAD to the drive unit 14.** (Col. 4, lines 27—34).

Recall that the PAD 12 has three main parts as illustrated in FIG. 4: (1) a **cylindrical neck 20 with a flange 22 at the bottom, implanted so that the neck protrudes through the skin 24**; (2) a replaceable turret 26 inside the neck; and (3) **an external part 18,** which connects to the drive unit's external drive line. The PAD is positioned near the patient's navel. During the implantation procedure, an **internal drive line 28** from the blood pump and the pacemaker leads 30 from the epicardium are **connected to the implanted part of the PAD** as illustrated prior to implantation in FIG. 5. (Col. 9, lines 45—54).

It is clear from Freed's description that the "second gas-line part 18" referred to by the Examiner is only external to the patient and not part-implantable within the patient's body and part-external to the patient's body as claimed. In addition, Freed's PAD 12, which includes a flange 16 in Figure 3 and flange 22 in Figure 4 and operates as the connector between the "second [external] gas-line 18" and "internal drive line 28", is implanted at the exit site of the patient where it extends through the surface of the skin 24. The PAD[/connector] 12 is clearly not "positioned fully within the body of the patient in spaced relation with an exit site in the body of the patient through which the second gas-line part is adapted to pass" as claimed.

The claimed configuration, which includes a connection between the two gas-lines being wholly implanted within the body of the patient and spaced from the exit site, advantageously

results in only a simple lead projecting through the skin of the patient at the exit site and tends to reduce the occurrence of infection at the exit site as a result. However, if the exit site were to become infected, the claimed configuration advantageously enables the second gas-line to be removed from the patient after disconnection from the first gas-line and, because the first gas-line and connector are positioned wholly within the patient and spaced apart from the infection zone, the configuration enables the first gas-line to be connected to a new, sterile second gas-line that can be brought out of the body at a new position.

In contrast, if the Freed device becomes infected, the connector (PAD 12) must be surgically removed, which can complicate the treatment of the infection. Moreover, if the Freed device becomes infected, the internal lead, i.e., internal drive line 28, which extends from the connector, i.e. PAD 12, at the exit site and up to and including the active component of the device, would need to be removed because it would be impossible to sterilize the lead in-situ.

Lastly, Freed clearly does not disclose a subcutaneous anchoring collar in spaced relationship with the exit site and the subcutaneous connection in the gas line. The collar or flange at base 16 is not in spaced relation with the exit site or the connector 12.

Accordingly, Freed fails to anticipate claim 1 and claims 2—10 by virtue of their dependence upon claim 1. It is believed that the present application is in condition for allowance and a favorable action is respectfully solicited.

Claims 6—8 have been rejected as unpatentable over Freed as obvious. As noted above, Freed fails to meet the limitations of claim 1 and thus cannot establish a prima facie case obviousness.

New claims 14—23 are patentable over Freed for at least the same reasons that claims

1—10 are patentable over Freed. It is, however, noted that claim 10 has been cast in Jepson form such that the preamble, which states that the claimed apparatus is an improvement in an "implantable medical device implanted within a body of a patient, the medical device including a percutaneous gas-line connecting the medical device to a gas driver located external to the body of the patient," constitutes a structural limitation in the claim. The nature and proper interpretation of Jepson-type claims is explained in Rowe w. Dror, 112 F.3d 473 (Fed. Cir. 1997), as well as in Section 608.01(m) of the Manual of Patent Examining Procedure.

In the Rowe case, the claims were directed to a "balloon angioplasty catheter" and the claims were rejected on the basis of a prior art balloon catheter designed for applying medicine into a body duct. The Federal Circuit plainly held that the preamble of the rejected claim which recited that it was an angioplasty catheter was a structural limitation which patentably distinguished it from the medication delivery balloon catheter of the reference. The distinction in the present case is much larger than that in Rowe. In the present case, the preamble to claim 14 recites that the apparatus is an implantable medical device implanted in the body of a patient and including a percutaneous gas line to connect it with a gas driver located external to the boday of the patient. The body of the claims goes on to recite the improvement to include a first gas-line part wholly implantable in the body, a second gas-line part implantable in part within the body, and wherein the connection between the first gas-line part and the second gas-line part is positioned fully within the body of the patient in spaced relation with an exit site in the body of the patient through which the second gas-line part passes.

In this regard, the casting of claim 10 in Jepson form such that the preamble to the claim recites an implantable medical device implanted in the body of a patient and including a

purcutaneous gas line must be given effect as a meaningful limitation in claims 14—23, and, thus, it is submitted that the casting of these claims in Jepson form removes any vestige of doubt about the inapplicability of Freed to the claimed inventions.

The Commissioner is authorized to charge a one month fee of **$60.00** to deposit account No. 15-0665 and any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,
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